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August 2, 2005

Arthur Neal, Director, Program Administration
National Organic Program, USDA-AMS-TMP-NOP
1400 Independence Ave., S.W.
Room 4008-So., Ag Stop 0268
Washington, DC 20250

Re: National Organic Program, Sunset Review

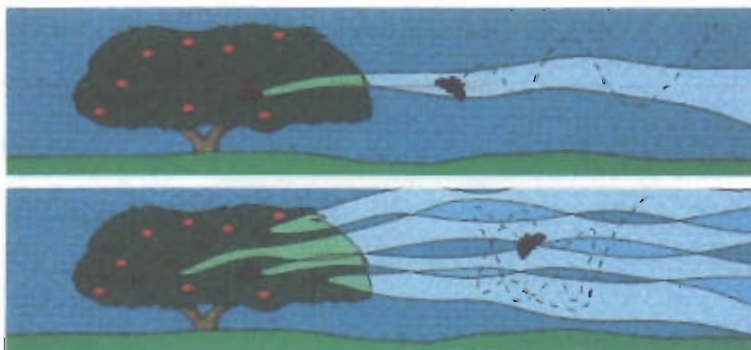
Dear Mr. Neal:

As the Registration Agent for Pacific Biocontrol Corp., I would like to comment in support of extending the existing exemption for pheromones as insect management (205.601(f)) on the National List of Allowed and Prohibited Substances.

Pacific Biocontrol is the distributor of the "Isomate®" mating disruption products. These products use the synthetic duplicate of a natural occurring compound, insect pheromone, to disrupt mating of target pests.

What is Pheromone? What is Mating Disruption?

Natural pheromone is produced and released by the female. The male uses the pheromone as an olfactory cue for locating the female prior to mating. Pacific Biocontrol's products contain the synthetic replica of the naturally occurring pheromone produced by the insect.



Top picture: a male moth easily finds the female by following the pheromone plume she emits.

Bottom picture: shows how Isomate® disrupts normal communication between male and female codling moths.

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This synthetic pheromone controls the population of the target pest by permeating the surrounding areas, and thus, disrupting the olfactory cues used by the male to locate the female. As result, the male does not find the female, and mating is disrupted.

How does this work with Pacific Biocontrol's Isomate products?

Pacific Biocontrol's technology consists of the synthetic pheromone being impregnated in a polyethylene tube. The grower applies the dispenser tubes uniformly throughout the treated area. Each tube slowly releases minute amounts of pheromone into the atmosphere, which affects the mating pattern of the target insect. This results in diminished reproductive success.



ISOMATE-CTT
applied with "hoop"
applicator in apples.

Each dispenser tube consists of the chemical blend that corresponds to the pheromone for the particular insect that it is targeting. Each of the chemicals is important in affecting the full range of behavioral events, which is important in successful sexual communication between males and females. This material is very specific to those insects that use the chemical blend as part of the sex pheromone. As the mode of action of the pheromone is not toxic, but behavioral, it is not expected that these biochemicals would pose any potential hazard to humans, environment, or non-target species.

Mating Disruption as a Key Component In Integrated Pest Management Programs

Mating disruption has become an effective method for control of many important insect pests. As of 1999 there were more than 60 mating disruption products registered with the US EPA. The number has increased over the past six years. Mating disruption is a key component in many area-wide integrated pest management programs often resulting in reduced use of toxic chemical insecticides. Furthermore, this technique has become an indispensable tool for organic growers.

Codling Moth Mating Disruption, as a Specific Example

Pacific Biocontrol Corporation develops and markets pheromone-based systems used for control of several important insect pests, including the codling moth, *Cydia pomonella*, and oriental fruit moth, *Grapholita molesta*.

The codling moth is a key pest of pome fruits throughout world and is primarily controlled by one or more applications of broad-spectrum insecticides. Much effort has been put into the development of alternative control methods due to limitations and disadvantages of conventional insecticides. Mating disruption has become an effective and economical method for controlling codling moth. The total pome fruit area treated with mating disruption formulations worldwide in 2004 is estimated at 126,000 hectares. In the USA the estimated area is 55,000 hectares.

Organic Codling Moth Mating Disruption and IPM

In the USA, the codling moth has been one of the most difficult pests to control by organic methods. Without chemical insecticides, pest numbers can increase exponentially. Most organically acceptable alternatives for codling moth control do not provide effective or economical control. These methods include: mass trapping, beneficial insects (including inundative release), microbial insecticides (Bt, virus), botanicals (ryania), sterile male release and parasitic nematodes. Sanitation (removal of infested fruit) and summer oils have provided better control but are still not adequate by themselves.

Organic options for codling moth control include the following:

- Mating Disruption
- Summer Oils
- Sanitation: remove infested fruit
- Sterile Males
- Trapping: larvae and adults
- *Bacillus thuringiensis* (Bt)
- Virus (CMGV)
- Nematodes
- Botanicals: ryania, rotenone, pyrethrum
- Parasites: *T. platneri*, *Ascogaster* sp.
- Predators: birds, beetles, spiders, ants, etc.

Mating disruption, either alone or in combination with other biological and cultural control methods, has proven to be the most effective tool for controlling codling moth in organic apples and pears. This technique is the basis for any codling moth management program in organic apples and pears – most other methods are used to supplement mating disruption.

Approximately 20,000 acres of organic apples and pears are grown in the USA. It is estimated that more than 95% of these acres are treated with some type of mating disruption formulation for codling moth control. In the USA it would be very difficult to grow an organic apple or pear for fresh market consumption without the use of mating disruption.

California Organic Tree Fruit Acreage - 2001

Apples	Pears	Stone Fruit	All Fruit
4529	842	3112	8662

Pheromones as Part of the Regulatory Relief under the US EPA

In 1995, the US EPA formed BPPD (Biopesticides and Pollution Prevention Division) to manage and accelerate the regulatory process for biologically-based pesticide products. The goal of the new Division was to streamline the process of registering biological products and to provide a consistently high quality of service to the producers of these types of products. Under BPPD, there are two sub-divisions, Microbials and Biochemicals. Pheromone products are reviewed under the Biochemicals sub-division.

The US EPA has assisted the regulatory relief for pheromones and other similar semiochemicals by recognizing the difference between semiochemicals and conventional chemical pesticides. "The Agency has assumed that pheromones and other similar semiochemicals are different from conventional synthetic pesticides, and has attempted to facilitate their registration with reduced data requirements and regulatory relief efforts." (*Federal Register*, 60, 168, pp. 45060-45062).

The first regulatory relief measures that the US EPA established for pheromone products were tolerance exemptions that included the following:

- (1) In 1994, arthropod pheromones in retrievably sized polymeric matrix dispensers. "In the proposal, EPA set forth its reasons for determining that a tolerance for these pheromone products is not necessary to protect public health." (*Federal Register*, 59, 61, pp. 14757-14759)
- (2) In 1995, lepidopteran pheromones in any mode application. "Lepidopteran pheromones that are naturally occurring compounds, or identical or substantially similar synthetic compounds, designated by an unbranched aliphatic chain (between 9 and 18 carbons) ending in alcohol, aldehyde or acetate functional group and containing up to 3 double bonds in the aliphatic backbone, are exempt from the requirement of a tolerance in or on all raw agricultural commodities." (*Federal Register*, 60, 168, pp. 45060-45062)

The EPA has recognized that pheromone products in retrievable sized, polymeric matrix dispensers pose minimal risk with their low use rates and significantly eased the regulatory guidelines for registering these types of products. "The Agency has recognized that a special category of pheromone products dispensed from larger sized polymeric matrices with low annual use rates represent minimal risk for dietary and environmental exposure and has greatly eased the burden to register these items." (*Federal Register*, 60, 168, pp. 45060-45062)

The US EPA has recognized that these types of pheromone products are expected to have no adverse effects and minimal exposure since they are very specific to the insect that they are controlling and have a small release rate in the environment. "Adverse effects on nontarget organisms (mammals, birds, and aquatic organisms) are not expected because these pheromones are released in very small amounts to the environment and act on a select group of insects." (*Federal Register*, 58, 234, pp. 64493-64494)

In Conclusion

Pheromones, used in mating disruption products, are the synthetic duplicate of natural occurring compounds. These types of products are a non-toxic, behavioral method for the control of insects. Mating disruption is an essential tool for pest management in organic production and is particularly important to organic growers who have fewer, control alternatives. The US EPA has recognized these types of products as being different from chemical pesticides. They are expected to pose minimal risk with their low use rates and are expected to have no adverse effects. Mating disruption products are designed to slowly release minute amounts and to be very specific to those insects that use the chemical blend as part of the sex pheromone. They do not affect the crop, the grower, the environment, or other non-target insects.

Therefore, I urge the National Organic Program to extend the existing exemption for pheromones as insect management (205.601(f)) on the National List of Allowed and Prohibited Substances.

Please contact me if you have any questions at my phone number or e-mail below. Thank you very much.

Yours Sincerely,

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